From: **OMEALY Mikell**

Eric Blischke/R10/USEPA/US@EPA To:

Subject: FW: my response to burt_ Final Draft ERA Package to EPA - CSM still needs work in my opinion

Attachments: pic11478.jpg

Eric - FYI, as I mentioned on the phone today.

----Original Message---

From: Jeremy_Buck@fws.gov [mailto:Jeremy_Buck@fws.gov] Sent: Monday, November 21, 2005 1:18 PM

OMEALY Mikell

Subject: my response to burt_ Final Draft ERA Package to EPA - CSM still needs work in my opinion

---- Forwarded by Jeremy Buck/OSO/R1/FWS/DOI on 11/21/2005 01:17 PM

Jeremy Buck

Shephard.Burt@epamail.epa.gov

To:

11/18/2005 07:14 cc:

Goulet.Joe@epamail.epa.gov

Subject: Re: Final Draft ERA Package to EPA - CSM still needs work in my opinion (Document link: Jeremy Buck)

Hey Burt-

I wanted to partly address your concerns on the significance issue. The definitions of a significant pathway are not intended to pre-judge whether or not a contaminant has reached effect levels, but attempts to describe that a contaminant has a "high likelihood" or "low likelihood", or potential, to reach an effect level based on the exposure route described. A fish will be exposed to many contaminants and thus experience a complete pathway, but many of those contaminants will be regulated, metabolized, or detoxified and not reach effect levels. So, we are trying to weed out those completed pathways that, based on literature and best professional judgement (BPJ), would be unlikely to reach effect levels. I don't really like the language much either because assessing "likelihood" is quite arbitrary and subjective (but at least not capricious!), but the intent was to identify those situations where we had a higher degree of confidence based on literature data, BPJ, and other completed risk assessments where effects from the receptor-contaminant pairings have been better documented. This allowed us to reduce the number of "complete and significance unknown" pairings. Therefoe, these definitions do not apply to what is currently occurring in the harbor, but rather on what could occur based on receptor-contaminant pairings in other studies. wanted to partly address your concerns on the significance issue.

I certainly am not opposed to changing the language, but I am not sure if changing it to "a significant proportion of the contaminant dose to which receptors are exposed" necessarily captures our intent. This seems to still relate to exposure, and after all, if we do not suspect or show effects can happen but rather can only show exposure, then pursuing a risk assessment would necessarily be supported.

If possible, I would like to come up with language that better indicates that the potential for effects is higher with one receptor-pathway pairing than another, and I think this is actually required before a risk assessment can be completed (i.e., I would follow through with many more pairings if I thought EPA would let me investigate exposure without showing effects or suspecting a potential for effects).

Also, we purposely stated in the definitions that "contaminant concentrations can reach effect levels solely by the proposed route or pathway under evaluation" in order to separate out the effects of multiple contaminants. We did not want to complicate the decision process with multiple contaminants, and we tried to capture the multiple contaminant aspects in the "Significance Unknown" definition by stating (as indicated in the textbox below) "however, the contaminant might contribute to effect levels when combined with other pathways or other contaminants." We can certainly change this as well with better wording wording.

It seemed that the process went smoother after we came up with these definitions, but I am certainly willing to change them as long as the wording captures some of the intent I indicated above, and we are able to describe something more than just a complete or incomplete pathway. Let me know what you think -jeremy

(Embedded image moved to file: pic11478.jpg)

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Subject: Re: Final

Draft ERA Package to EPA - CSM still needs work in my opinion

Hello all,

- I will be out of the office all day Monday, Nov. 21st meeting with NOAA and USFWS on the ESA biological assessment of Oregon's water quality criteria, and have a meeting Tuesday, Nov. 22 on a small food web model I ran at a RCRA site on the Duwamish River, and thus will have little time to review the documents given your time frame.
- I do want to voice one concern regarding what I believe to be a significant omission in the conceptual site model figure: the absence of upland soil (above riparian zone soil) as an exposure medium. Granted evaluation of upland soil is outside the LWG's purview, nevertheless, it is a source of contaminants to several of the receptors shown on the CSM (i.e. terrestrial plants, mink, several of the bird species, and possibly adult life stages of some frogs and salamanders).
- It is much easier to explain to people outside the CSM development process that under the current organization of responsibilities at the site, LWG is not responsible for evaluating ecological risks at the upland portions of the site (a management decision) than it will be to explain why an exposure medium responsible for complete and significant exposure pathways for multiple ecological receptors across the entire length of the site is completely absent from the CSM. Upland soil was present in earlier drafts of the CSM, I don't know when or who decided to pull soil from the CSM.

This omission is all the stranger given that one of the original objectives of our revising the CSM was to make explicit the link between the upland portions of the site and the Willamette River. I cannot support sending out the CSM to the LWG in its present state without amending the CSM to correct this omission.

I also have concerns regarding the definitions of significant exposure pathways on two grounds, both relating to the use of wording implying a pathway is significant if concentrations are high enough to reach effect levels. Defining significant exposure as that which rresult in contaminants reaching effect levels prejudges the conclusions of the ecological risk assessment. Specifically, the definition implies that significant exposure routes have already reached adverse effect levels, a conclusion that has not yet been made. While the definition as written is appropriate for a CSM written for a NRDA, where an injury has already been identified, it is inappropriate to prejudge the conclusions of a risk assessment in this manner. I recommend that the definitions of significance be reworded to state that a significant proportion of the contaminant dose to which receptors are exposed be the definition of significant. This rewording does not imply toxicity, it merely implies that a substantial proportion of the contaminant dose to which receptors are exposed comes from a given exposure pathway. Determining whether or not an exposure reaches toxic levels is the job of the toxicity assessment and risk characterization portions of the ecological risk assessment, not the CSM. I also have concerns regarding the definitions of significant exposure

the significance definition states that "contaminant Secondly, the significance definition states that "contaminant concentrations can reach effect levels solely by the proposed route or pathway under evaluation." In the real world, contaminant levels in a single medium may not be at sufficient elevated concentrations to elicit adverse effects, whereas the sum of exposures from multiple media may be sufficient to elicit adverse effects. The definitions as written do not allow for the possibility that multiple routes of exposure may be needed to supply the contaminant dose required to elicit adverse effects in some receptors. This is really what we mean when we judge an exposure pathway as complete but insignificant: the pathway is not responsible for an appreciable proportion of the dose of contaminant to which a receptor is exposed.

Best regards,

Burt Shephard

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